

510(k) Summary for the LITE Pelvic Floor Repair Kits

Date Prepared: September 13, 2011

SEP 14 2011

A. Sponsor

Boston Scientific Corporation
Urology and Gynecology Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

Michelle Berry
Senior, Regulatory Affairs Specialist
508-683-4941
or
Donna Gardner
Director, Regulatory Affairs
508-683-4398

C. Device Name

Tradename: LITE Pelvic Floor Repair Kits
Common/usual name: Surgical Mesh
Classification Name: **OTP**- Mesh, Surgical, Polymeric and
OTP – Mesh, Surgical, gynecologic, for pelvic organ
prolapse, transvaginally placed
21 CFR 878.3300, Class II

D. Predicate Device(s)

Tradename: Pinnacle and Uphold Pelvic Floor Repair Kits
Common/usual name: Surgical Mesh
Classification Name: **OTP**- Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II
Premarket Notification: Boston Scientific, K071957, K081048, K091131

Tradename: Novasilk Mesh
Common/usual name: Surgical Mesh
Classification Name: **OTP**- Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II
Premarket Notification: K053414

Tradename: Restorelle Polypropylene Mesh
Common/usual name: Surgical Mesh
Classification Name: **OTP, OTO** Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II
Premarket Notification: K092207

E. Device Description

The proposed devices were submitted to introduce lightweight versions of previously cleared pelvic floor repair kits: Pinnacle Anterior/Apical, Pinnacle Posterior, Pinnacle Duet and Uphold Vaginal Support System. The proposed mesh configurations were designed for performing transvaginal vaginal wall repair to facilitate treatment of anterior, apical and posterior prolapse repairs. These devices are sterile, single use devices, consisting of one or two light-weight synthetic mesh assemblies and a needle holder.

The mesh assemblies consist of a macroporous polypropylene knitted mesh body with integrated legs that are protected by disposable polymer sleeves. At the distal end of the disposable polymer sleeve is a lead with needle designed for use with the Capio™ Open Access Suture Capturing Device. The disposable lead was designed to facilitate the passage of the proposed mesh through bodily tissues for placement.

F. Intended Use

The proposed LITE mesh kits are intended for tissue reinforcement and stabilization of fascial structures of the pelvic floor for vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

G. Technological Characteristics

The proposed device has the same mesh fiber materials and fiber diameter as the predicates but is knit with a larger pore size to create a lighter, lower density mesh.

H. Substantial Equivalence/ Performance Testing (Bench)

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" and "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh", a direct comparison of key characteristics demonstrates that the proposed mesh is substantially equivalent to the predicate mesh in terms of intended use, technological characteristics, and performance characteristics tested.

Boston Scientific conducted mechanical performance and biocompatibility testing to demonstrate the equivalence of the LITE mesh to the predicate devices.

The mesh mechanical performance testing included mesh thickness, pore size, density, tensile strength, stiffness, burst strength, tear strength, suture pullout strength, and mesh flexibility. In addition, Boston Scientific evaluated the tensile strengths of the mesh assembly including the components of the leg assemblies (needle, lead, dilator, protective sleeve and leader loop). Boston Scientific also evaluated the force to remove the leg assemblies from the mesh.

Biocompatibility testing on the LITE kits' materials of construction included cytotoxicity, sensitization, irritation, acute systemic toxicity, sub acute toxicity, genotoxicity and implantation.

The results of the performance testing demonstrate equivalence of the LITE Pelvic Floor Repair kits to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ms. Michelle Berry
Sr. Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

SEP 28 2012

Re: K103426
Trade/Device Name: LITE Pelvic Floor Repair Kits
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP
Dated: September 2, 2011
Received: September 6, 2011

Dear Ms. Berry:

This letter corrects our substantially equivalent letter of September 14, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

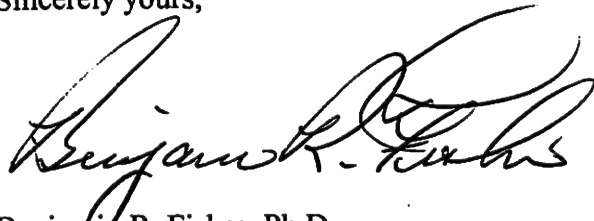
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with the first name "Benjamin" being the most prominent.

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known): K103426

Device Name: LITE Pelvic Floor Repair Kits

Indications For Use:

The proposed LITE Pelvic Floor Repair Kits are indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor for vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.


Prescription Use X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K103426